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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,528	05/22/2001	Daniel W. Nebert	91830.0476945	1421
7590	05/26/2005		EXAMINER	
FROST BROWN TODD LLC 2200 PNC Center 201 East Fifth Street Cincinnati, OH 45202-4182			BERTOGLIO, VALARIE E	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/863,528	NEBERT, DANIEL W.
	<b>Examiner</b>	<b>Art Unit</b>
	Valarie Bertoglio	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on 07 March 2005.  
2a)  This action is FINAL.                    2b)  This action is non-final.  
3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

- 4)  Claim(s) 1-37 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-37 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## **Application Papers**

- 9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 22 May 2001 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date

- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant's reply filed 03/07/2005 has been received. Claims 1-4,11-23,25,26 and 34-37 have been amended. Claims 1-37 are pending and under consideration in the instant office action.

***Specification***

The objection to the specification is withdrawn in light of Applicant's amendment to the Table 1.

***Claim Objections***

The objection to claims 11 and 18 is withdrawn in light of the amendments to the claims.

***Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-37 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained. Applicant's arguments filed 03/07/2005 have been fully considered but they are not persuasive. The rejection is maintained for reasons of record set forth on pages 2-7 of the office action mailed 09/08/2004.

In response to the rejection on the grounds that the specification has failed to teach that the transgene construct encompassed by the claims are responsive to contaminants in vivo when the transgene is incorporated into the genome of a fish or other aquatic organism, Applicant has argued that the claims do not require that the transgene be stably incorporated into the genome of the host.

In response, claims 1 and 2 recite that step (a) forms a transgenic organism. The specification defines transgenic animal at paragraph [0022] as containing “one or more transgenes within its genome”. Other references in the specification, specifically paragraphs [0018-0020] clearly indicate the term transgenic organism is referring to a stable transgenic organism comprising a transgene that is incorporated in the genome. Accordingly, as set forth on page 5 paragraph 2 of the previous office action mailed 09/08/2004. Only one construct was shown to be used in making a transgenic organism as defined by the specification (paragraph [0081]). No transgenic fish were demonstrated to contain transgenes within their genomes that were responsive to contaminants, failing to overcome to unpredictability set forth in the with respect to transgene expression (see paragraph bridging pages 5-6 of the office action mailed 09/08/2004).

When the claims are interpreted as encompassing transiently transfected fish, harboring the transgenes extrachromosomally as is argued by Applicant, Applicant further argues that any ectopic background expression or variability in expression of the transgenes would not affect the claimed methods and is not of concern because, upon transfection, “animals will be selected for those with proper expression of the transgene and will be individually correlated to a known standard in order to use for detection of a contaminant” (page 9, paragraph 4 of Applicant’s remarks).

In response, for Applicants’ arguments to hold true, the “known standard” must be the background level of expression of the transgene in each individual fish in the absence of contaminants. The claimed methods do not require a determining step wherein a background level of expression is determined prior to exposure to contaminants. In fact, claims 1(e) and 2(e)

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refer to correlating the detected expression to “known standards”. The background level of expression of a construct is not a “known standard” and the claims do not require that expression be determined for each individual organism prior to exposure to a contaminant. Therefore, if the claims encompassed transiently transfected aquatic organisms, they do not require a step of determining transgene expression levels prior to exposure to contaminants and therefore, transiently transfected organisms would not be enabled in the methods as claimed.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicant's amendments to the claims.

The rejection of claims 18-34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained, in part, as set forth on page 8, paragraph 5 of the previous office action mailed 09/08/2004.

Applicant's remarks have been fully considered and are persuasive with respect to all aspects of the rejection of claims 18-34 with the exception of that set forth on page 8, paragraph 5 of the previous office action mailed 09/08/2004.

Applicant has argued that ACE1 is the correct nomenclature for genes as is found at <http://www.gene.ucl.ac.uk/nomenclature>. Applicant notes that ACE1 refers to angiotensin I converting enzyme.

In response, this argument is not persuasive because not all of the annotations listed in claim 18 can be found on this website. It is not clear what each of the abbreviations is notating. Therefore, the rejection of claim 18 and dependent claims 19-34 is maintained.

The following rejection is necessitated by amendment.

Claims 18-34 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18, as amended, reads “at least one response element selected from the group consisting of...” Not all of the listings in the group are response elements. In fact, it appears most of represent gene names, not response elements. The list appears to be a compilation of gene names and response elements, all abbreviated, making it unclear what Applicants are claiming as their invention. Claims 19-34 depend from claim 18.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

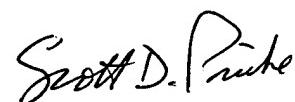
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio  
Examiner  
Art Unit 1632



SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER